

REMARKS/ARGUMENTS

I. Claim Amendments

Claims 2-12, 18-28, and 32-45 have been canceled from the application. Claims 1, 13-15, 17, and 30 have been amended to replace "other anti-diabetic compositions" with "dipeptidyl peptidase-IV inhibitors". Support for this amendment is found in the specification in at least paragraphs 25 and 28. Claims 1, 13-15, 17, and 30 have also been amended to replace "comprising" with "consisting essentially of". Support for this amendment is found in the specification in at least paragraphs 8 -10. Accordingly, these amendments do not constitute new matter.

II. Rejections Under 35 USC § 101 and 112

Claims 30 and 31 have been amended to overcome the Examiner's rejections under 35 U.S.C. §§ 101 and 112. The amended claims set forth a method having specified steps. Accordingly, Applicant believes these rejections have been overcome and respectfully requests that the rejections be withdrawn. Applicant also requests that claims 30 and 31 be properly regarded as method claims.

Claim 16 has been amended to correct the Markush group. Respectfully, Applicant believes these amendments overcome the Examiner's indefiniteness rejection under 35 U.S.C. § 112 and requests that this rejection be withdrawn.

III. Rejection Under 35 USC § 102(b)

It is respectfully requested that the rejection of claims 1, 14-17, 30-31, and 46 under 35 USC § 102(b) as being anticipated by Anderson, *et al.* be reconsidered in view of the amendments to the claims and upon consideration of the reasons discussed below and be withdrawn. As amended, the claims recite a pharmaceutical composition

or a method of treatment using a composition which consists essentially of balaglitazone and one or more dipeptidyl peptidase-IV inhibitors. Use of the "consisting essentially of" transition phrase limits the scope of the claims to a composition containing balaglitazone, one or more dipeptidyl peptidase-IV inhibitors, and only those additional components that "do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). Every embodiment of Anderson requires a protein tyrosine phosphatase inhibitor, as set forth in Formula 1 (pages 15-17). Because the inclusion of a protein tyrosine phosphatase inhibitor in the present invention would materially affect the basic and novel characteristics of the claimed invention, Anderson does not meet the limitations of the amended claims. Accordingly, Anderson cannot anticipate the presently-claimed invention. Applicant respectfully requests that the anticipation rejection be withdrawn.

IV. Rejection Under 35 USC § 103(a)

It is respectfully requested that the rejection of claims 1-46 under 35 USC § 103(a) as being obvious over Anderson, *et al.* and Bussolari, *et al.* be reconsidered in view of the amendments to the claims and upon consideration of the reasons discussed below and be withdrawn. As set forth above, Anderson does not disclose a pharmaceutical composition or a method of treatment using a composition which consists essentially of balaglitazone and one or more dipeptidyl peptidase-IV inhibitors. There is no suggestion in Anderson to modify the teaching such that balaglitazone and one or more dipeptidyl peptidase-IV inhibitors should be administered without a protein

tyrosine phosphatase inhibitor. In fact, the teachings of Anderson require the use of a protein tyrosine phosphatase inhibitor in every embodiment.

Bussolari was cited by the Examiner for its teaching of 28B-L-Lys-29B-Pro human insulin. Bussolari does not teach or suggest a pharmaceutical composition or a method of treatment using a composition which consists essentially of balaglitazone and one or more dipeptidyl peptidase-IV inhibitors. Without such a disclosure or suggestion in either reference, or the combination thereof, the invention cannot be considered obvious over Anderson and Bussolari. Applicant respectfully requests that the obviousness rejection be withdrawn.

V. Obligation under 37 C.F.R. § 1.56

Applicant acknowledges its duty to under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made.

In view of the foregoing arguments, Applicant respectfully submits that the rejected claims are patentably distinct over the references cited by the Examiner and meet all other statutory requirements. We believe that the present Application is now in complete condition for allowance and, therefore, respectfully request the Examiner to reconsider the rejections in the Office Action and allow this Application.

We invite the Examiner to telephone the undersigned should any issues remain after the consideration of this response. Please charge any additional fees that may be required to Deposit Account No. 50-2548.

Respectfully requested,

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Date

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